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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/078,649	02/19/2002	Yun Hwang Choe	213.1077-CTML-U	5287
22856	7590	08/10/2006	EXAMINER	
MUSERLIAN, LUCAS AND MERCANTI, LLP 475 PARK AVENUE SOUTH NEW YORK, NY 10016			CHANNAVAJJALA, LAKSHMI SARADA	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/078,649

Applicant(s)

CHOE ET AL.

Examiner

Lakshmi S. Channavajjala

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 and 5-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5-22-06 has been entered.

Claims 1-3 and 5-24 are pending in the claims.

The following is a new rejection:

***Claim Rejections - 35 USC § 112***

Claim 15 recites the limitation "E38" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Instant claim describes the variable D1, which is different from the D1 described in claim 1. Instant claim 15 is indirectly dependent upon claim 1. Claim 1 recites D1 as formula IV or formula V and does not include the description of that provided in claim 15. In particular the variable E38 substituted on N atom of claim 15 is not supported by the description of claim 1 because according claim 1 the variable J is NR12 but not NHR12. Thus, it is not clear instant claim

***Claim Rejections - 35 USC § 103***

Claims 1-3 and 5-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/53951 (WO).

WO '951 teaches terminally branched polymeric linkers and polymeric conjugates containing the linkers for forming long-acting conjugates of bioactive materials. In particular, WO teaches compounds of formula I (page 3), where the variables J, E, Y, M, Z etc., (described on pages 3-5). WO further teaches that R1 is a polymeric residue, which includes polyalkylene oxides such as polyethylene glycols (page 12); and also teaches the molecular weight of polymers in the range 2,000 to 100,000 (page 13, lines 15-25). WO also teaches the linking a number of drugs such as podophyllotoxin, gemcitabine, ciclopirox etc to be delivered with the prodrug compounds (page 16-17). With respect to the instant  $[R2-C-R3]_m$ , WO teaches q=zero or positive integer (page 4, line 19).

WO differs from the instant claims in the presence of an aryl group in the variable D1 or D2. While instant claims recite an aryl group, WO does not specifically exemplify compounds with aryl groups in the variables D1 or D2. However, WO suggests that the variable J can be  $\begin{matrix} E_1 \\ | \\ E_2 - C - \\ | \\ E_3 \end{matrix}$ , in which s E1-4 include moieties such as aryl, arylalkyl or substituted aryl groups (page 7, lines 14-19). Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to include an aryl or aryl alkyl or a substituted aryl groups as one of the E2-4 on the variable J and still achieve a prodrug having same efficiency in delivering the desired drug because WO teaches prodrug compounds with an alkyl or aryl or aryl alkyl substitution on the

moiety E1-4 as equivalent in their efficiency. Thus, a skilled artisan would have expected to achieve effective drug transport systems with an aryl-containing moiety on any of the E1-4.

### ***Response to Arguments***

Applicant's arguments filed 5-22-06 have been fully considered but they are not persuasive.

Applicants' arguments regarding the rejection of claims under 35 USC 112, first paragraph is moot because the rejection has been withdrawn.

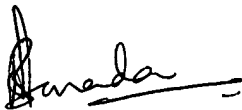
Claims 1-3 and 5-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/53951 (WO).

Applicants argue that instant claims require either formula IV or V for variables D1 and D2, which are not taught by WO. It is argued that the presence of aromatic groups facilitates the benzyl-elimination reaction to regenerate or release the drug or active moiety. However, the arguments are not persuasive because WO teaches that the variable J can include variables E2-4, which can independently include an aryl or a substituted aryl or aryl alkyl groups (see above explanation). Thus, WO suggests that alkyl as well as aryl or substituted aryl groups are equally effective as polymeric drug carriers and thus have the capability of functioning in the same way as argued by applicants.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala  
Examiner  
Art Unit 1615  
August 7, 2006